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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/358,321	07/21/1999	KITISRI SUKHAPINDA	50.447	1398

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/358,321

Applicant(s)

SUKHAPINDA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,12 and 13 is/are rejected.
- 7) ☒ Claim(s) 1,6,7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed July 23, 2002, paper no.19, has been entered.

Claim 11 is cancelled.

Claims 1, 2, 3, 4, 6, 7 and 8 are newly amended.

Claims 1-10 and 12-13 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 1, 6 and 7 are objected to because they recite the transit peptide of a nonelected invention (SEQ ID NO:56, directed to maize palmitoyl ACP thioesterase). Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 5 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to progeny derived from the plant cell of claim 2 or claim 12.

The claimed invention lacks written description under current written description guidelines. The claim is drawn to progeny plants having undisclosed identifying characteristics whereby only one parent is known. Applicant should note that no identifying characteristics are set forth for the progeny. If the claimed progeny plant itself cannot be identified by

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characteristics clearly disclosed in the specification, then it would be impossible to determine whether or not a plant of unknown parentage is covered by the claim. Thus progeny plants which are not disclosed by any identifying characteristics are not considered to be possessed by Applicant. Absent further guidance, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genotypic or phenotypic characteristics of the progeny plants obtained. Breeding techniques can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring are highly unpredictable, especially in view of the fact that no identifying characteristics for the progeny plants are disclosed in the specification or set forth in the claims. Accordingly, there is a lack of written description for the claimed progeny plants, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed progeny (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 1-10 and 12-13 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule of SEQ ID NO:31 encoding a single-chain Fv antibody having the amino acid sequence of SEQ ID NO:32, and a method of decreasing the steady state level of maize stearoyl-ACP Δ -9 desaturase in maize cells using the nucleic acid molecule of SEQ ID NO:31, does not reasonably provide enablement for other antibodies or fragments thereof and methods utilizing other constructs comprising other nucleic acid sequences encoding other antibodies or antibody fragments, for the reasons of record set forth in the office action mailed January 18, 2002.

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Applicants' arguments filed July 23, 2002, have been fully considered but they are not persuasive.

Applicants argue that they have amended the scope of their claims to recite what transit peptides the anti-transit peptide must bind, thus limiting the scope of the claims to what the specification reasonably enables. Applicants point out that claim 1 originally recited that the anti-transit antibodies should bind to any transit peptide, whereas amended claim 1 is limited to antibodies that bind a specific transit peptide (reply pages 3-4).

While amended claim 1 is limited to antibodies that bind a specific transit peptide, the specification discloses only one nucleic acid encoding an antibody that binds to the maize stearoyl-ACP Δ -9 desaturase transit peptide and that decreases the steady state level of maize stearoyl-ACP Δ -9 desaturase in a maize plant cell. The disclosure of a single nucleic acid that performs the desired function does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, the identity of other nucleic acids encoding an antibody that binds to the maize stearoyl-ACP Δ -9 desaturase transit peptide and that decreases the steady state level of maize stearoyl-ACP Δ -9 desaturase in a maize plant cell, because the ability of an antibody to both bind to a transit peptide and to decrease the steady state level of the transit peptide's cognate protein is unpredictable. Binding is not the same as neutralizing and does not automatically downregulate a specific activity or function.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "associated", is withdrawn in light of the amendment of claim 1.

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Claim 1 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "having the ability to bind to a transit peptide", for the reasons of record set forth in the office action mailed January 18, 2002.

Applicants' arguments filed July 23, 2002, have been fully considered but they are not persuasive.

Applicants point to the definition of antibody found in the paragraph bridging pages 4 and 5, which states that "antibody" includes immuno-reactive fragments, segments, etc. Applicants argue that the definition and the guidance throughout the specification relating to this point demonstrate that the phrase "having the ability to bind to a transit peptide" applies to both the "antibody" and the "fragment thereof" (reply page 5).

That the specification states that "antibody" includes immuno-reactive fragments, segments, etc. does not overcome the rejection, as the claims are not limited to antibody fragments that are immuno-reactive. Furthermore, immuno-reactive fragments does not mean that the fragments will bind to the same target as the whole antibody.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "directs" a passenger protein, is withdrawn in light of the amendment of claim 1.

Claims 1 and 10 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "fragment thereof", for the reasons of record set forth in the office action mailed January 18, 2002.

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Applicants' arguments filed July 23, 2002, have been fully considered but they are not persuasive.

Applicants point to the definition of antibody found in the paragraph bridging pages 4 and 5, which explains that only immunologically-active fragments are included. Applicants also point to the discussion of antibody fragments on page 21, and argue that based on the cited passages and the mature state of the field, the ordinarily skilled immunologist will readily understand the meaning of immunologically-active antibody fragment (reply pages 5-6).

The explanation in the specification that only immunologically-active fragments are intended to be included in the instant invention does not overcome the rejection, as claims 1 and 10 are not limited to immunologically-active antibody fragments.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the indefinite article "a" in "a nucleic acid construct", is withdrawn in light of the amendment of claim 2.

The rejection of claims 3 and 4 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the indefinite article "a" in "a plant cell". is withdrawn in light of the amendment of claims 3 and 4.

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The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the noun "dicotyledon" to modify the noun "cell", is withdrawn in light of the amendment of claim 3.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the noun "monocotyledon" to modify the noun "cell", is withdrawn in light of the amendment of claim 4.

Claims 5 and 13 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "derived", for the reasons of record set forth in the office action mailed January 18, 2002.

Applicant's arguments filed July 23, 2002, have been fully considered but they are not persuasive.

Applicants because claim 2 in essence claims a plant cell transformed by the nucleic acid construct of claim 1, the derived plant or progeny in claim 5 refers to a plant regenerated from the transformed cell, or to plants bred with the transformed plant, both of which must possess the recombinant phenotype. Applicants assert a similar argument for claim 13.

While claim 2 from which claim 5 depends is limited to a plant cell transformed by the nucleic acid construct of claim 1, and while claim 8 from which claim 5 ultimately depends is limited to a method in which a plant cell is transformed by the nucleic acid construct of claim 1, the plants of claims 5 and 13 are no so limited, and it cannot be presumed that plants and progeny "derived" from a plant cell transformed by the nucleic acid construct of claim 1 would

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necessarily comprise the nucleic acid construct of claim 1. Furthermore, the plants of claims 5 and 13 are not limited to plants that possess the recombinant phenotype, or any particular phenotype.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "a maize plant of claim 5", is withdrawn in light of the amendment of claim 6.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the indefinite article "a" in "a maize plant", is withdrawn in light of the amendment of claim 7.

Claim 10 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "is a single chain antibody molecule", for the reasons of record set forth in the office action mailed January 18, 2002.

Applicant's arguments filed July 23, 2002, have been fully considered but they are not persuasive.

The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "said epitope", is withdrawn in light of the cancellation of claim 11.

The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in light of the amendment of claim 8.

Newly amended claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "immunologically functional antibody or fragment thereof". It is unclear what type of immunologic function is intended, as antibodies mediate more than one type of immunological function. It is also unclear whether "immunologically functional" applies to the antibody only, or to the antibody and the fragment thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Artsaenko et al. (The Plant Journal, Vol. 8, No. 5, pages 745-750, 1995).

The claims are drawn to progeny derived from the plant cell of claim 2 or claim 12.

Artsaenko et al. teach tobacco plants transformed with a DNA sequence encoding an antigen-binding single chain F_v protein (scF_v) (page 748 column 2 first full paragraph). There are insufficient identifying characteristics set forth in the claims to distinguish the claimed progeny plants from the transgenic plants of the prior art. The claims do not specifically recite a progeny plant whereby all of the identifying characteristics of the parent plant are retained. The breeding

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techniques used to produce the claimed progeny plants can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring are highly unpredictable. None of the identifying features which distinguish Applicant's plants from those of the prior art are set forth (see written description rejection *supra*). Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of any prior art that teaches transgenic plants. See *in re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process of making the product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562, F.2d 1252, 195 USPQ 430 (CCPA 1977).

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

October 19, 2002


PHUONG T. BUI
PRIMARY EXAMINER 10/21/02